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EXAMINER	
MEHTA, ASHWIN D	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,418	MORELL ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-91* is/are pending in the application.

4a) Of the above claim(s) *76-79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-72,74,75 and 80-91* is/are rejected.

7)☐ Claim(s) *73* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9122002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 1-5, 7, 8, 10, 11, 33-38, and 41-46 (all now cancelled and replaced with new claims 67-75 and 80-91) and SEQ ID NO: 3 in the paper submitted January 20, 2004 is acknowledged. The traversal is on the ground(s) that the claims of Group X (claims 22-25, now cancelled and replaced with new claims 76-79) share the special technical feature of new claim 67 (response, page 12, 2nd full paragraph). This is not found persuasive because Group II already comprises a method of using the nucleic acid molecule of claim 67 (or claim 1). Claims 76-79 are directed to another method of use. A group may not comprise two different methods of using the same product.

The requirement is still deemed proper and is therefore made FINAL. Claims 76-79 have been withdrawn for being directed to a non-elected invention. Claims 67-75 and 80-91 have been examined in this Office action. Non-elected subject matter should be removed from claim 73.

Specification

2. Page 8, line 12 of the specification recites a non-existent GenBank accession number. Clarification is required. New matter must be avoided.

3. The specification fails to comply with 37 CFR 1.821-1.825. The brief descriptions to Figures 2, 3, 7, and 9 do not recite the sequence identifiers of the sequences that appear in those

figures. Sequences also appear in numerous other locations (e.g., pages 12, 14, 15, 22, 23, 25, 26, 28, 29, 37, 38, 67-70, 74) that are not referred to by their sequence identifiers.

4. Figures 2, 3, 7, and 9 contain multiple views that are labeled with a letter. However, the brief descriptions of those figures in the specification do not recite those labels. See 37 CFR 1.74.

Claim Objections

5. Claims 68, 72-75, 82, 87, and 88 are objected to for the following reasons:

In claims 68, 72, 75: the claims recite amino acid sequences without referring to them by their sequence identifiers, as required by 37 CFR 1.821(d).

Claim 73 is objected to as being dependent upon a rejected base claim. The claim also encompasses non-elected sequences.

Claim 74 objected to because of the following informality: in line 2, "isolated" should be --isolated--.

Claim 82 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 80 indicates that the method is for modifying the starch content and/or composition of one or more tissues or organs of a plant, comprising the step of expressing a nucleic acid molecule in said plant. Claim 82 broadens the scope of claim 80 by introducing the nucleic acid molecule into an isolated plant cell, tissue, organ, or organelle.

Further, claim 80 does not encompass modifying the starch content or composition of an isolated plant cell, tissue, organ, or organelle. It is suggested that the term "further" in line 1 of claim 82 be deleted, and that the following recitation be added at the end of the claim: --, and regenerating a plant from the cell, tissue, organ, or organelle comprising the introduced nucleic acid molecule--. Note that claim 83 would need to be cancelled with the amendment to claim 82.

Claims 87 and 88 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). In the interest of compact prosecution, the claims have been examined as if they did not recite "of claim 67."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 68-70, 72, and 80-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 recites the limitation "the wheat starch synthase" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim or parent claim 67.

In claim 80: the recitation, "wheat starch synthase isoenzyme of said plant" in lines 8-9 and lines 10-11 renders the claim indefinite. The preamble of the claim indicates that the method is for modifying starch content in a plant. However, parts (ii) and (iii) indicate that the plant is

wheat. This renders the claim indefinite because it is not clear if the method is limited to wheat plants.

In claim 84: the recitation, "wherein the nucleic acid molecule is introduced to the plant cell, tissue, organ, or organelle by introgression" renders the claim indefinite. "Introgression" or "introgressive hybridization" is defined in the art as hybridization between two species in which the genes of one species gradually diffuse into the gene pool of another (Holmes, S., Henderson's Dictionary of Biological Terms, 9th Ed., Van Nostrand Reinhold Co., New York, 1979, page 218). Claim 84 is dependent on claim 82, which indicates that the recited plant parts are in isolated form. It is not clear what is meant by introgression of isolated plant cells, tissues, organs, or organelles. The metes and bounds of the claim are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 68, 69, 71, 72, 75, and 80-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated nucleic acid molecule comprising a nucleotide sequence encoding any polypeptide having any starch synthase activity or a

nucleotide sequence complementary thereto, said nucleotide sequence (i) having at least 85% identity to the nucleotide sequence of the protein-encoding region of SEQ ID NO: 3, or (ii) encoding a polypeptide having at least 85% identity to SEQ ID NO: 4, or (iii) being complementary to (i) or (ii); or wherein the polypeptide comprises one or more sequences recited in claim 68 or also those recited in claim 72; or wherein said polypeptide is a wheat starch synthase II polypeptide; or any probe or primer comprising at least any 15 contiguous nucleotides of said isolated nucleic acid molecule; or a method of modifying the starch content and/or composition of one or more tissues or organs of a plant, comprising the step of expressing in said plant any nucleic acid molecule for a time and under conditions sufficient for the enzyme activity of one or more starch synthase isoenzymes to be modified, wherein said nucleic acid molecule is (i) said isolated nucleic acid molecule, (ii) a fragment of (i) comprising a nucleotide sequence which is expressed to down-regulate the expression of any endogenous wheat starch synthase isoenzyme of said plant, or (iii) a fragment of (i) encoding any functional wheat starch synthase isoenzyme of said plant; any transgenic plant comprising said isolated nucleic acid molecule; progeny or a propagule of said transgenic plant comprising said nucleic acid molecule; any gene construct or vector comprising said nucleic acid molecule or said probe or primer.

The specification asserts that starch synthases extend regions of α-1,4-glucan by transferring the glucoysl moiety of ADP-glucose to a pre-existing α-1,4-glucan. Four classes of starch synthases have been identified in plants: GBSS, SSI, SSII, and SSIII (page 8, lines 8-15). The specification indicates that on SDS-PAGE, several protein bands from the matrix of wheat starch granules can be visualized, including an 85 kDA band containing a class II branching enzyme and an unidentified polypeptide (page 8, line 21 to page 9, line 1). The specification

indicates that monoclonal antibodies against Sgp-1 polypeptides, (belonging to the class of WSII starch synthases) were used to probe a wheat endosperm cDNA expression library. Three plaques were identified, and the DNA within sequenced. One clone, "WSSIIpI," contained an 85 bp insert with homology to maize SSIIa. This was used to probe a second endosperm cDNA expression library from *Triticum aestivum* Wyuna (page 58, lines 15-23). One of the hybridizing clones, designated "wSSIIA," is 2842 bp in length and set forth in SEQ ID NO: 3. Bases 89-2485 of SEQ ID NO: 3 encode the amino acid sequence of SEQ ID NO: 4 (page 59, lines 1-3). SEQ ID NO: 4 shares 95.7% to 96.6% identity with the amino acid sequences encoded by two other cDNA clones that hybridized with the WSSIIpI probe, wSSIIB and wSSIID (SEQ ID NO: 1 and SEQ ID NO: 5, respectively, both non-elected; page 58, lines 27-30; page 59, lines 5-14). wSSIID is a partial cDNA clone (page 59, lines 5-7). The specification also indicates that the mRNA for WSSII can be detected in leaves, pre-anthesis florets, and endosperm in Northern hybridizations. The specification does not indicate which SSII is being referred to, although it also indicates that the probe used was from the wSSIIB cDNA (page 61, lines 10-14). The specification indicates that comparison of wheat GBSS, SSI, SSII, and SSIII sequences revealed eight highly conserved domains (page 67, lines 24-25). The sequences for these motifs in wSIIA are shown in the paragraph bridging pages 68-69, regions 1-7. The specification also indicates that wSSIIA shares 76.1% identity with the maize SSIIa and 76.3 % identity with maize SSIIb (Table 5, page 71). The molecular weight of the precursor wSSIIA is 87,229 Da and mature wSSIIA is 81,164 Da. However, the molecular weight has previously been measured as 105 kDA (page 73, lines 19-21).

However, the specification does not teach nucleotide sequences encoding a starch synthase and having at least 85% identity to SEQ ID NO: 3, or encoding an amino acid sequence having at least 85% identity to SEQ ID NO: 4, wherein the polypeptide comprises one or more sequences from (a)-(h) recited in claim 68, or (a)-(f) recited in claim 72. The recited sequences in claims 68 and 72 do not appear in the wheat starch synthase II polypeptides disclosed in the specification. The specification teaches that the aforementioned sequences recited in claims 68 and 72 appear in SSIII enzymes (page 67, lines 25-27). The specification does not correlate the structure of any nucleotide sequence encoding a polypeptide comprising the aforementioned amino acid sequences with the starch synthase activity possessed by SEQ ID NO: 4.

The method of claim 80 encompasses fragments of the isolated nucleic acid molecule of claim 67 that encode a functional wheat starch synthase. However, the specification does not describe the structure of any fragment of SEQ ID NO: 3 that encodes a functional starch synthase. The only structures that are correlated with the activity of starch synthase described by the specification are those of SEQ ID NOs: 1 (non-elected) and 3, which encode full-length proteins. The specification discusses amino acid sequences within wSSIIa that are conserved (pages 60, 68-69). However, the structures of these domains are not correlated with any functional activity. The specification indicates that the C-terminal domain of starch synthases comprise the catalytic domain (page 66). However, this domain is not a functional starch synthase enzyme.

Claim 75 is drawn to a probe or primer comprising at least 15 contiguous nucleotides of the isolated nucleic acid of claim 67, and comprising specified nucleotide sequences. However, SEQ ID NO: 3 does not contain the nucleotide sequences listed in SEQ ID NOs: 25-28, or

nucleotide sequences encoding amino acid sequences of parts (a)-(h) of part (v) of claim 75. The specification indicates that SEQ ID NOs: 25-28 were used as primers in PCR reactions to amplify fragments from non-elected SEQ ID NO: 1 (page 62, lines 7-13). As SEQ ID NO: 3 does not contain the nucleotide sequences of SEQ ID NOs: 25-28, or the sequences of parts (v)(a-h) of claim 75, the specification does not describe probes or primers from nucleotide sequences having 85% identity to SEQ ID NO: 3, or nucleotide sequences encoding an amino acid sequence having 85% identity to SEQ ID NO: 4, wherein the encoded polypeptide is correlated with the starch synthase activity of SEQ ID NO: 4. Given the breadth of the claims, it is submitted that the specification fails to provide an adequate written description of the multitude of nucleotide sequences encompassed by the claims.

8. Claims 68, 69, 71, 72, 75, and 80-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleotide sequences encoding SEQ ID NO: 3, probes and primers comprising at least 15 contiguous nucleotides of SEQ ID NO: 3, a method of modifying the starch content and/or composition of one or more tissues or organs of a plant comprising expressing SEQ ID NO: 3 to co-suppress an endogenous wheat starch synthase or expressing SEQ ID NO: 3 in antisense orientation, does not reasonably provide enablement for nucleotide sequences having at least 85% identity with SEQ ID NO: 3 or encoding a polypeptide having at least 85% identity with SEQ ID NO: 4 wherein the polypeptide comprises the sequences recited in parts (a)-(h) in claim 68 or (a)-(f) of claim 72, or wherein the nucleotide sequence comprises the sequences set forth in SEQ ID NOs: 25-28, or fragments that encode a functional wheat starch synthase; the method of claim 80 where the fragment of part (ii) is

expressed to down regulate the expression of an endogenous wheat starch synthase in any other manner; or said method wherein isolated plant cells, tissues, organs, or organelles are introgressed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any isolated nucleic acid molecule comprising a nucleotide sequence encoding any polypeptide having any starch synthase activity or a nucleotide sequence complementary thereto, said nucleotide sequence (i) having at least 85% identity to the nucleotide sequence of the protein-encoding region of SEQ ID NO: 3, or (ii) encoding a polypeptide having at least 85% identity to SEQ ID NO: 4, or (iii) being complementary to (i) or (ii); or wherein the polypeptide comprises one or more sequences recited in claim 68 or also those recited in claim 72; or wherein said polypeptide is a wheat starch synthase II polypeptide; or any probe or primer comprising at least any 15 contiguous nucleotides of said isolated nucleic acid molecule; or a method of modifying the starch content and/or composition of one or more tissues or organs of a plant, comprising the step of expressing in said plant any nucleic acid molecule for a time and under conditions sufficient for the enzyme activity of one or more starch synthase isoenzymes to be modified, wherein said nucleic acid molecule is (i) said isolated nucleic acid molecule, (ii) a fragment of (i) comprising a nucleotide sequence which is expressed to down-regulate the expression of any endogenous wheat starch synthase isoenzyme of said plant, or (iii) a fragment of (i) encoding any functional wheat starch synthase isoenzyme of said plant; any transgenic plant comprising said isolated nucleic acid

molecule; progeny or a propagule of said transgenic plant comprising said nucleic acid molecule; any gene construct or vector comprising said nucleic acid molecule or said probe or primer.

The specification teaches the nucleotide sequence (SEQ ID NO: 3) of a cDNA encoding a wheat starch synthase II (SEQ ID NO: 4), as discussed above.

However, the specification does not enable the isolated nucleic acid molecules of claim 68 wherein the encoded polypeptide comprises any of the sequences recited in parts (a)-(h). Some of the same sequences also recited in claims 72 and 75. The specification teaches that those sequences are found within WSIII polypeptides (page 67, lines 25-27), whereas SEQ ID NO: 4 is a WSII polypeptide. Given the teachings of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed nucleic acid molecule comprising wherein the encoded polypeptide comprises the aforementioned amino acid sequences and wherein the polypeptide has the activity of SEQ ID NO: 4. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. The specification also does not teach that SEQ ID NO: 3 comprises the nucleotide sequences set forth in SEQ ID NOs: 25-28. Rather, those sequences are within non-elected SEQ ID NO: 1. The specification teaches that SEQ ID NOs: 25-28 were used as primers in PCR reactions to amplify fragments from SEQ ID NO: 1 (page 62, lines 7-13).

The specification also fails to enable the method of modifying starch content and/or starch composition comprising expressing a fragment of the nucleic acid molecule encompassed by claim 67 wherein the fragment encodes a functional wheat starch synthase isoenzyme. The specification does not provide any guidance concerning fragments of the coding region of SEQ

ID NO: 3 that encodes an amino acid sequence that retains the activity of SEQ ID NO: 4. The specification discusses regions of SEQ ID NO: 4 that are conserved in other starch synthases (pages 60, 68-69). The specification also indicates that that the catalytic domain of starch synthases is located in the C-terminus (page 66). However, these conserved domains and the catalytic domain alone do not form functional enzymes. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine the fragments of the claimed nucleic acid molecules that still encode a functional wheat starch synthase isoenzyme.

The specification also does not enable the claim method when the fragment of part (ii) of claim 80 is a ribozyme. The specification provides only a general discussion of what a ribozyme is (paragraph bridging pages 48-49). However, the specification does not enable the use of ribozymes with the claimed method. The prior art has shown that the use of ribozymes to decrease the expression of specific targets in plants has not been successful. Mazzolini et al. (Plant Mol. Biol., 1992, Vol. 20, pages 715-731) attempted to use ribozymes to inhibit the activity of a target GUS gene in plant protoplasts. However, GUS activity was not decreased, and the authors conclude that the ability of ribozymes to cleave their substrate mRNA in vitro is essential but not sufficient to ensure efficient inhibition of the target in a plant cell (pages 722-723, 726-729). Kull et al. (J. Genet. Breed. 1995, Vol. 49, pages 69-76) constructed ribozymes intended to cleave Waxy RNA transcripts in potato plants. However, while in vitro experiments identified one catalytic RNA that cleaved its target, no activity could be detected in vivo (pages 71-72, 75). The instant specification does not provide any teachings that overcome the difficulties of the prior art in designing and using ribozymes to down regulate the expression of a

specific target in plant cells or plants. In the absence of further guidance, undue experimentation would be required by one skilled in the art to make and use ribozymes to down regulate the expression of starch synthases in plants.

The specification also does not enable the claimed method when the fragment of part (ii) of claim 80 is a gene-targeting molecule. The specification defines that gene targeting as the replacement of an endogenous gene sequence within a cell by a related DNA sequence with which it hybridizes (page 50, lines 7-17). The discussion of gene targeting provides no information at all as to the steps that one skilled in the art must follow to cause such a replacement to occur. Puchta (Plant Mol. Biol., 2002, Vol. 48, pages 173-182) discusses the state of gene replacement by homologous recombination in plants, and teaches that efficient gene targeting techniques in higher plants have not yet been achieved. Puchta teaches, for example, that improvements to gene targeting in animals have not been successful in plants (page 173), that extending the length of homology in the transferred DNA to up to 22 kb did not result in higher frequencies (page 174). Puchta discusses that results of gene targeting in Arabidopsis, involving the AGL5 MADS-box gene, have been controversial, and that no statistically sound conclusion as to the frequencies of targeting could be drawn from this single event (paragraph bridging pages 174-175). Terada et al. (Nature Biotech., 2002, Vol. 20, pages 1030-1034) also address the reports of gene targeting in Arabidopsis, and also assert that no one has yet repeated the experiments, and that the authors of one of those reports also detected the occurrence of undesirable events, including ectopic recombination and/or simultaneous ectopic integration of the transgene used (page 1030). While Terada et al. teach a method for homologous recombination in rice, it is noted that this method was not known at the time the instant invention

was filed. In the absence of further guidance, undue experimentation would be required by one skilled in the art to use gene targeting with the claimed method to modify the starch content and/or starch in plants. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Further, claim 84 introduces the limitation of requiring the nucleic acid molecule to be introduced into an isolated plant cell, tissue, organ, or organelle by introgression. As discussed above, introgression is the hybridization between two species in which the genes of one species gradually diffuse into the gene pool of another (Holmes, S. *supra*). The specification, however, is silent as to how isolated cells, tissues, organ, or organelles are crossed to produced cells, tissues, organs, or organelles that comprise the nucleic acid molecule, and such a method is not taught in the art. Further, claims 84 and 85 recite that the nucleic acid molecule is to be introduced into an organelle. The specification does not teach how the nucleic acid molecule would down-regulate the expression of an endogenous wheat starch synthase isoenzyme from organelles. See Genentech, Inc. V. Novo Nordisk, A/S, *supra*. Furthermore, claim 80 indicates that the nucleic acid molecule expressed in the plant will modify the enzyme activity of one or more starch synthase isoenzymes. However, the specification does not discuss methods in which activity itself of starch synthases will be modified, as opposed to the decrease in the level of expression of starch synthase II. Nothing at all is mentioned in the specification that teaches one skilled in art to affect the enzyme activity of any starch synthase. For example, co-factors or other products that are required for enzymatic function are not taught in the specification or the prior art. In the absense of further guidance, undue experimentation would be required by one

skilled in the art to determine products that affect the enzyme activity of any starch synthase, and determine the nucleotide sequence that encodes it, so that it may be used in the claimed method. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 67, 68, 70, 72, 74, 75, 80-83, and 85-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Block et al. (WO/9745545).

The claims are broadly drawn towards any isolated nucleic acid molecule comprising a nucleotide sequence encoding any polypeptide having any starch synthase activity or a nucleotide sequence complementary thereto, said nucleotide sequence (i) having at least 85% identity to the nucleotide sequence of the protein-encoding region of SEQ ID NO: 3, or (ii) encoding a polypeptide having at least 85% identity to SEQ ID NO: 4, or (iii) being complementary to (i) or (ii); or wherein the polypeptide comprises one or more sequences recited in claim 68 or also those recited in claim 72; or any probe or primer comprising at least any 15 contiguous nucleotides of said isolated nucleic acid molecule; or a method of modifying the starch content and/or composition of one or more tissues or organs of a plant, comprising the step of expressing in said plant any nucleic acid molecule for a time and under conditions sufficient for the enzyme activity of one or more starch synthase isoenzymes to be modified, wherein said nucleic acid molecule is (i) said isolated nucleic acid molecule, (ii) a fragment of (i) comprising a nucleotide sequence which is expressed to down-regulate the expression of any endogenous wheat starch synthase isoenzyme of said plant, or (iii) a fragment of (i) encoding any functional wheat starch synthase isoenzyme of said plant; any transgenic plant comprising said isolated nucleic acid molecule; progeny or a propagule of said transgenic plant comprising said nucleic acid molecule; any gene construct or vector comprising said nucleic acid molecule or said probe or primer.

Block et al. teach the isolation and sequences of a cDNA (SEQ ID NO: 6) encoding a wheat starch synthase (SEQ ID NO: 5). The nucleotide sequence of SEQ ID NO: 6 and the amino acid sequence of SEQ ID NO: 5 have at least 85% identity to instant SEQ ID NO: 3 and SEQ ID NO: 4, respectively. SEQ ID NO: 6 of Block et al. also comprises one or more amino

acid sequences of the Markush group of instant claims 68 and 72, including at least six of the sequences shown in (i)-(p) of claim 68. SEQ ID NO: 5 itself can be considered to be a probe or primer. Block et al. indicate that initially a partial sequence consisting of bases 1084 to 2825 of SEQ ID NO: 5 was determined, which is at least 15 contiguous nucleotides. Block et al. also teach vectors comprising the cDNA operably linked to a promoter, and comprising an origin of replication; transgenic plants comprising, progeny of said plant, or propagules of said plants, comprising SEQ ID NO: 5. A method which results in the modification of the starch content and/or composition of plants is also taught, the method comprising expressing SEQ ID NO: 5 or fragments thereof in plants in antisense orientation, or in sense orientation, to cause the co-suppression of an endogenous starch synthase. Plants in which the method can be practices include wheat (pages 6-8, 16-18, 29-36, 41-44, 63-66).

10. Claims 67, 68, 70, 72, 74, 75, 80-83, and 85-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Block et al. (U.S. Patent No. 6,307,125).

The claims are broadly drawn towards any isolated nucleic acid molecule comprising a nucleotide sequence encoding any polypeptide having any starch synthase activity or a nucleotide sequence complementary thereto, said nucleotide sequence (i) having at least 85% identity to the nucleotide sequence of the protein-encoding region of SEQ ID NO: 3, or (ii) encoding a polypeptide having at least 85% identity to SEQ ID NO: 4, or (iii) being complementary to (i) or (ii); or wherein the polypeptide comprises one or more sequences recited in claim 68 or also those recited in claim 72; or any probe or primer comprising at least any 15 contiguous nucleotides of said isolated nucleic acid molecule; or a method of modifying the

starch content and/or composition of one or more tissues or organs of a plant, comprising the step of expressing in said plant any nucleic acid molecule for a time and under conditions sufficient for the enzyme activity of one or more starch synthase isoenzymes to be modified, wherein said nucleic acid molecule is (i) said isolated nucleic acid molecule, (ii) a fragment of (i) comprising a nucleotide sequence which is expressed to down-regulate the expression of any endogenous wheat starch synthase isoenzyme of said plant, or (iii) a fragment of (i) encoding any functional wheat starch synthase isoenzyme of said plant; any transgenic plant comprising said isolated nucleic acid molecule; progeny or a propagule of said transgenic plant comprising said nucleic acid molecule; any gene construct or vector comprising said nucleic acid molecule or said probe or primer.

U.S. Patent No. 6,307,125 is a continuation of WO/9745545, and contains the teachings discussed above (col. 3., line 58 to col. 4, line 55; col. 7, line 18 to col. 9, line 33; col. 13, line 48 to col. 14, line 49; col. 14, line 63 to col. 17, line 48; col. 19, line 65 to col. 21, line 37; claims).

11. Claim 73 is objected to, claims 67-72, 74, 75, and 80-91 are rejected, and claims 76-79 are withdrawn.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ashwin Mehta whose telephone number is 571-272-0803. The examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached

at 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 1, 2004

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